DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive SE
Bothell, WA 98021-4421

Telephone: 425-486-8788
FAX: 425-483-4996

April 5, 2000

VIA FEDERAL EXPRESS

In reply refer to Warning Letter SEA 00-35

Thad C. Pound, President
Kirkland Custom Seafoods
640 8th Avenue
Kirkland, Washington 98083

WARNING LETTER

Dear Mr. Pound:

We inspected your firm located at 640 8th Avenue, Kirkland, Washington on February 7-9, and 14, 2000, and found that you have serious deviations from Title 21 of the Code of Federal Regulations (21 CFR) Part 123 - Fish and Fishery Products (Seafood HACCP regulations). A FDA 483 form (copy enclosed) listing the deviations was presented to you at the conclusion of the inspection. These deviations cause your canned tuna, canned smoked tuna, and hot smoked salmon to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find this Act and the Seafood HACCP regulations through links in FDA's homepage at www.fda.gov.

The deviations were as follows:

1. You must have a HACCP plan to control any food safety hazards that are reasonably likely to occur, in order to comply with 21 CFR 123.6(b). Your firm does not have a HACCP plan for canned tuna and canned smoked tuna to control for the food safety hazard of histamine.

2. You must have monitoring records which document the actual values and observations obtained during monitoring, in order to comply with 21 CFR 123.6(c)(7). You did not have monitoring records to document time and temperature for the cooking critical control point to control for pathogen growth, specifically *Clostridium botulinum* in your hot smoked salmon product since the previous inspection on June 8-10, 1999. You corrected this deviation during the inspection by starting to keep records, but we are concerned that in eight months time, you did not have such records. This deviation has been previously brought to your attention in letter's sent to you on October 25, 1999 and June 24, 1998.

3. You must have sanitation control records that document monitoring and corrections, in order to comply with 21 CFR 124.11(c). You did not have sanitation control records for the eight areas of sanitation since the previous inspection on June 8-10, 1999. You corrected this deviation during the inspection by starting to keep records, but we are concerned that in eight months time you did not keep such records. This deviation has been previously brought to your attention in letter's sent to you on October 25, 1999 and June 24, 1998.

The above violations are not meant to be an all-inclusive list of deficiencies in your plant. It is your responsibility to assure that all of your products are in compliance with applicable statutes enforced by the FDA, including the Seafood HACCP regulations and the Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food regulations in 21 CFR 110. We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product and/or enjoin your firm from operating.

Please respond in writing within three (3) weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation such as your revised HACCP plan and copies of your monitoring records, or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

Please send your reply to the Food and Drug Administration, Attention: Lisa M. Elrand, Compliance Officer, 22201 23rd Drive SE, Bothell, Washington 98021-4421. If you have any questions regarding any issue in this letter, please contact Lisa Elrand at (425) 483-4913.

Sincerely,

Kristy D. Ries
for Charles M. Breen
District Director

Enclosures:
Form FDA 483
21 CFR PART 123
Section 402 of the Federal Food, Drug, and Cosmetic Act

cc: WSDA with disclosure statement